UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

County of Lake, Ohio v. Purdue Pharma L.P., et al.,
Case No. 18-op-45032 (N.D. Ohio)

County of Trumbull, Ohio, v. Purdue Pharma L.P., et al.,
Case No. 18-op-45079 (N.D. Ohio)

"Track Three Cases"

MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

PHARMACY DEFENDANTS' MOTION FOR RECONSIDERATION OR CERTIFICATION AND SUPPORTING MEMORANDUM

Pursuant to Federal Rule of Civil Procedure 54(b), Pharmacy Defendants[1] move for reconsideration of the Court's August 6, 2020 Order denying their Motion to Dismiss Plaintiffs' Second Amended Complaints (Doc. 3403) ("Order"), which reached the unprecedented conclusion that pharmacy-registrants are required by the Controlled Substances Act to affirmatively "use" the prescription records they collect to monitor all controlled-substance prescriptions for "red flags" of diversion. In reaching this conclusion, the Court relied on a

[1] "Pharmacy Defendants" are CVS Health Corporation, CVS Pharmacy, Inc., CVS Indiana, L.L.C., CVS Rx Services, Inc., CVS TN Distribution, L.L.C., and Ohio CVS Stores L.L.C. (collectively, "CVS"); Rite Aid Corp., Rite Aid Hdqtrs. Corp., Rite Aid of Ohio, Inc., Rite Aid of Maryland, Inc., and Eckerd Corp. d/b/a Rite Aid Liverpool Distribution Center (collectively, "Rite Aid"); Walgreen Boots Alliance, Inc., Walgreen Co., and Walgreen Eastern Co. (collectively, "Walgreens"); Giant Eagle, Inc., and HBC Service Company (collectively, "Giant Eagle"); and Walmart Inc. f/k/a Wal-Mart Stores, Inc., Wal-Mart Stores East, LP, WSE Management Inc., WSE Investment LLC, and Wal-Mart Stores East, Inc. (collectively, "Walmart").

regulation that was not raised by Plaintiffs and that was not the subject of briefing. The Court also relied on an interpretation of another regulation that conflicts with a ruling issued last week by another district court. *See United States v. McKesson Corp.*, No. 19-CV-02233, 2020 WL 4805034, at *4 (N.D. Cal. Aug. 18, 2020). If the Court will not reconsider its conclusion, then Pharmacy Defendants respectfully request that, given the novelty of this interpretive question and its far-reaching consequences for this litigation and beyond, the Court certify the Order for interlocutory appeal so the Sixth Circuit can resolve this controlling question of law.

Pharmacy Defendants further seek reconsideration on the ground that the Order used an inapplicable Ohio rule of construction to interpret an Ohio statute. Pharmacy Defendants ask that this issue too be reconsidered or, at minimum, certified to the Ohio Supreme Court.

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STATEMENT OF ISSUES AND SUMMARY OF ARGUMENT

In denying Pharmacy Defendants' motion to dismiss the "Track 3" cases, the Court held that the Controlled Substances Act ("CSA") or DEA regulations promulgated under the CSA require pharmacy-registrants to "use" their prescription records "to monitor for questionable prescriptions." Doc. 3403 at 15. Specifically, the Court concluded, pharmacy-registrants have a "corporate-level obligation to design and implement systems, policies, or procedures to identify red flag prescriptions." *Id.* at 25; *see also id.* at 21–22. The Court also appeared to hold that "[c]omputer algorithms" are a mandatory component of these systems. *Id*. at 23 n.27. These requirements are a judicial creation found nowhere in the text of the CSA, never previously suggested by the expert agency that Congress charged with implementing the CSA, and not supported by a single judicial opinion or administrative decision in any jurisdiction. The holding runs contrary to decades of pharmacy law, infringes on the prerogatives of the legislative and executive branches, and threatens the balance between ensuring that patients have access to prescribed medications and preventing diversion.

The Court built this novel corporate-level "system" obligation on three assumptions: (1) that record-keeping requirements imply a legal obligation to *use* those records to detect suspicious prescriptions; (2) that the regulation requiring "effective controls . . . against . . . diversion," 21 C.F.R. § 1301.71(a), implies that pharmacy-registrants have a corporate-level duty to monitor for "red flag" prescriptions; and (3) that "Agency decisions" "require[]" pharmacy registrants to check each controlled-substance prescription for red flags at the corporate level. Doc. 3403 at 24–25. Each assumption is clearly erroneous. The mere fact that pharmacy-registrants have certain record-keeping obligations does not imply a completely separate legal obligation to "use" this "collect[ed] . . . data" in particular ways. *Id.* at 15. As another court

recognized just last week, "Section 1301.71(a) does not require any specific security measures." *United States v. McKesson Corp.*, No. 19-CV-02233, 2020 WL 4805034, at *4 (N.D. Cal. Aug. 18, 2020). What is more, DEA, through notice-and-comment rulemaking, made the policy judgment that pharmacy-registrants would *not* be subject to the corporate-level "system" obligations imposed on manufacturer- and distributor-registrants. And DEA has never said that corporate pharmacy-registrants (as opposed to their pharmacists) "are obligated to check for . . . red flags of possible diversion" before a pharmacist dispenses any controlled substance. Doc. 3403 at 22.

If the Court will not reconsider its Order, then Pharmacy Defendants respectfully request that, given the novelty of this interpretive question and the newly discovered regulatory obligations it imposes on pharmacies, the Court certify the Order for interlocutory appeal so the Sixth Circuit can resolve this controlling question of law. The Order also erred by relying on an inapplicable Ohio rule of construction to interpret an Ohio statute. The Court should also reconsider this issue or certify it to the Ohio Supreme Court.

BACKGROUND

Pharmacy Defendants moved to dismiss Plaintiffs' Second Amended Complaints on June 16, 2020. Doc. 3340. On August 6, 2020, the Court denied the motion. Doc. 3403. This motion concerns two of its conclusions.

First, the Court concluded that pharmacy-registrants have a "corporate-level obligation to design and implement systems, policies, or procedures to identify red flag prescriptions." *Id.* at 25; *see also id.* at 21–22. The Court reached this conclusion based on (1) the notion (not advanced by Plaintiffs in their briefing) that the CSA's record-keeping obligations imply an unstated obligation to "use" the "data" that is thereby collected, *see id.* at 15, 17; (2) the general

regulation stating that all registrants "shall provide effective controls and procedures to guard against theft and diversion of controlled substances," 21 C.F.R. § 1301.71(a); and (3) its belief that "Agency decisions" "require[]" pharmacy-registrants at the corporate level "to check for and conclusively resolve red flags of possible diversion" before dispensing any controlled substance, *id.* at 22–25. Despite a DEA regulation that unambiguously assigns a "corresponding responsibility" for "the proper prescribing and dispensing of controlled substances" to "the *pharmacist* who fills the prescription," 21 C.F.R. § 1306.04(a) (emphasis added), the Court concluded that "pharmacies" bear the same responsibility independent of their pharmacists, Doc. 3403 at 18–19.

Second, the Court rejected Pharmacy Defendants' Ohio-law argument. Although a common law claim for absolute public nuisance based on alleged violations of controlled-substance laws is unprecedented in Ohio, and although Ohio Rev. Code § 4729.35 expressly provides that only injunctive relief is available for this type of public nuisance, the Court applied the following rule of construction: "[T]he Legislature will not be presumed or held to have intended a repeal of the settled rules of the common law, unless the language employed by it clearly expresses or imports such intention." Doc. 3403 at 6 (quoting *State ex rel. Morris v. Sullivan*, 90 N.E. 146, syllabus ¶ 3 (Ohio 1909)). The Court rejected Pharmacy Defendants' argument that the availability of an absolute public nuisance claim based on alleged violations of controlled-substance laws is not a "settled rule[] of common law" merely because Ohio courts have recognized *other* and unrelated common law claims for absolute public nuisance "based on a defendant's unlawful conduct." *Id.* at 6–7. And the Court did not address Pharmacy Defendants' argument that the *Morris* rule of statutory construction properly applies only when

the statute in question is tangential to the rule of common law that is precluded. Doc. 3379 at 2–3 & n.3 (citing *Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 920 & n.6 (N.D. Ohio 2009)).

STANDARD

"District courts have authority both under common law and [Fed. R. Civ. P.] 54(b) to reconsider interlocutory orders and to reopen any part of a case before entry of final judgment." *Rodriguez v. Tenn. Laborers Health & Welfare Fund*, 89 F. App'x 949, 959 (6th Cir. 2004). Reconsideration is warranted where, among other things, "there is . . . a need to correct a clear error or prevent manifest injustice." *Louisville/Jefferson Cnty. Metro Gov't v. Hotels.com, L.P.*, 590 F.3d 381, 389 (6th Cir. 2009) (quoting *Rodriguez*, 89 F. App'x at 959). A court may grant a motion for reconsideration if it "calls . . . attention to an argument or controlling authority that was overlooked or disregarded in the original ruling, presents evidence or argument that could not previously have been submitted, or successfully points out a manifest error of fact or law." *Jackson v. City of Cleveland*, 219 F. Supp. 3d 639, 642 (N.D. Ohio 2016) (internal quotation marks omitted).

Under 28 U.S.C. § 1292(b), a district court may certify an order for interlocutory appeal if three conditions exist: "[1] the order involves a controlling question of law [as] to which there is [2] substantial ground for difference of opinion and . . . [3] an immediate appeal may materially advance the termination of the litigation." *In re Trump*, 874 F.3d 948, 951 (6th Cir. 2017) (emphasis omitted). "[D]istrict courts should not hesitate to certify an interlocutory appeal" when "[t]he preconditions for § 1292(b) review" are "satisfied." *Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100, 110–11 (2009); *see also Ahrenholz v. Bd. of Trs. of Univ. of Ill.*, 219 F.3d 674, 677 (7th Cir. 2000) (Posner, J.) ("It is equally important . . . to emphasize the duty of

the district court . . . to allow an immediate appeal to be taken when the statutory criteria are met.").

Federal courts faced with novel and unsettled questions of law may avail themselves of state procedures allowing for certification of questions to the state's highest court. *See Arizonans for Official English v. Arizona*, 520 U.S. 43, 79 (1997); *Grover by Grover v. Eli Lilly & Co.*, 33 F.3d 716, 719 (6th Cir. 1994) ("Certification has proved to be an important tool for federal courts . . . since it frees them from having to speculate how state courts will decide important questions of state law."). "Speculation by a federal court about the meaning of a state statute in the absence of prior state court adjudication is particularly gratuitous when . . . the state courts stand willing to address questions of state law on certification from a federal court." *Brockett v. Spokane Arcades, Inc.*, 472 U.S. 491, 510 (1985) (O'Connor, J., concurring). The Ohio Supreme Court may answer a question of state law certified to it by a federal court if the question may be determinative and there is no controlling precedent in the decisions of the Ohio Supreme Court. Ohio S. Ct. Prac. R. 9.01.

ARGUMENT

I. The Court Should Reconsider Its Order Denying the Motion to Dismiss.

When it comes to the role of pharmacies and pharmacists under the laws pertaining to controlled substances, Congress and DEA have struck an important and delicate balance. An overly intrusive pharmacy (or pharmacist) risks disrupting the doctor-patient relationship, improperly overriding the physicians' expertise, and interfering with patients' access to medications they need. The complexity of this balance is shown by the dilemma in which Pharmacy Defendants find themselves: At the same time that Plaintiffs here ask the Court to re-write the law to *require* corporate-level dispensing policies, Pharmacy Defendants' voluntary

adoption of corporate-level dispensing policies for opioid prescriptions has been met with class action litigation alleging that such policies lead chain pharmacies to unlawfully refuse to fill valid prescriptions. *See* Complaint, *Smith v. Walgreens Boots All., Inc. et al.*, No. 3:20-cv-5451 (N.D. Cal. Aug. 6, 2020); Complaint, *Fuog v. CVS Pharmacy, Inc. et al.*, No. 1:20-cv-337 (D.R.I. Aug. 6, 2020). The American Medical Association and several state pharmacy and medical boards have also opposed Pharmacy Defendants' voluntary efforts to impose data-driven policies that go "beyond a pharmacist's corresponding responsibility,"[2] arguing, in part, that such policies impermissibly interfere with medical practice.

When an expert agency (like DEA) is charged with administering a technical regime (like the regulation of controlled substances), "judges ought to refrain from substituting their own interstitial lawmaking for that of" the agency. *Ford Motor Credit Co. v. Milhollin*, 444 U.S. 555, 568 & n.12 (1980). The errors of law and fact detailed below yielded an Order that departs from this principle. Never before has any regulator or court suggested that pharmacies are required either to aggregate and analyze prescription data to search for "red flags" or to implement systems for monitoring controlled-substance prescriptions over and above the individualized judgment of licensed pharmacists.[3] More fundamentally, no such requirement can be found in the text of the CSA or any of its implementing regulations. *Cf. FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000) ("In [a court's] anxiety to effectuate the congressional

[2] *E.g.*, Letter from James L. Madara, Exec. VP & CEO, Am. Med. Ass'n to Paul Beahm, SVP, Health & Wellness Ops., Walmart, Inc. (Oct. 3, 2018), https://searchlf.ama-assn.org/%E2%80%8Cundefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-10-3-Letter-to-Walmart-FINAL.pdf.

[3] By contrast, it is widely recognized and remarked that States have chosen to implement prescription drug monitoring programs—databases that "track[] controlled substance prescriptions in a state" and can "facilitate a nimble and targeted response" to "prescribing and patient behaviors" to reduce substance abuse. *E.g.*, CDC, *Prescription Drug Monitoring Programs (PDMPs)*, https://www.cdc.gov/drugoverdose/pdmp/states.html.

purpose of protecting the public, [it] must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.").

The only statutory text the Court mentioned in its "Pharmacy Duties" analysis was the provisions charging DEA (by delegation from the Attorney General) with discretion over whether to issue or deny a pharmacy's registration. Doc. 3403 at 14 (citing 21 U.S.C. §§ 822, 823(f), 824(a)(4)). The regulations that the Court relied on are non-dispositive factors that DEA is to consider when exercising this statutory authority to determine whether a pharmacy's continued registration is in the public interest. A court cannot graft onto those factors entirely new substantive rules of conduct that have not been duly promulgated by the agency itself.[4] For one thing, "[t]raditional concepts of due process incorporated into administrative law preclude an agency from penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule." *Satellite Broad. Co. v. FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987). DEA has never even suggested, much less provided notice of, the Court's newly discovered requirement that corporate pharmacy-registrants maintain data-based systems to identify "suspicious" prescriptions. And even if 21 C.F.R. § 1301.71(a)'s instruction that all registrants "provide effective controls and procedures to guard against . . . diversion" could arguably serve as a textual hook for such an expectation (it cannot), "agencies, not courts, retain control over which permissible reading of the regulations they will enforce . . . since it is the agencies, not the courts, that have the technical expertise and political authority to carry out statutory mandates." *Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1327 (D.C. Cir. 1995); *see also McKesson Corp.*, 2020 WL 4805034, at *4 ("Section 1301.71(a) does not require any specific security measures and

[4] Excerpts of the DEA regulations discussed in this memorandum are attached as Exhibit A.

instead grants the Administrator discretion to decide whether a [registrant] is substantially compliant with the CSA . . . .").

Moreover, if the Court does not reconsider its Order, it will upend long-standing pharmacy operations. Each and every pharmacy-registrant, large and small, would be compelled to implement some sort of "tool otherwise unavailable to its pharmacists," Doc. 3403 at 24, that would sift through historical prescription records to identify potential signals that their customers (or their customers' prescribers) might be engaged in unlawful diversion of controlled substances. Not only that, but the pharmacy-registrant would be obliged to use this tool to "check" each new prescription—in real time, while patients wait for their medications—against the records of past prescriptions, even when an expert professional pharmacist perceives nothing suspicious about the circumstances under which the prescription is presented. *Id.* at 21–22.

Because the clear errors described below produced a decision that radically departs from established guidance as to how federal controlled-substance law applies to pharmacies, the Court should reconsider its Order.

A. The Court's Conclusion That the CSA or DEA Regulations Require Pharmacy-Registrants to "Use" Their Prescription Records "to Monitor for Questionable Prescriptions" Is Based on Manifest Errors of Fact and Law.

The Court reasoned that three elements of the controlled-substance regulatory scheme add up to a requirement that corporate pharmacy-registrants "use" their prescription records "to monitor for questionable prescriptions." Doc. 3403 at 15. Those three elements are: (1) the existence of record-keeping requirements; (2) the requirement that all registrants "provide effective controls and procedures to guard against theft and diversion," 21 C.F.R. § 1301.71(a); and (3) "Agency decisions" that, the Court believed, "require[]" corporate pharmacy-registrants

to check each controlled-substance prescription for red flags. Doc. 3403 at 24–25. With respect to each, the Court's reasoning is founded on clear errors.

1. The fact that pharmacy-registrants are required to keep certain records does not imply a separate, unstated legal obligation to "use" this "collect[ed] data."

The Court concluded that an obligation to use the information contained within dispensing records to "identify[] suspicious prescribing and dispensing activity" necessarily follows from the record-keeping requirements themselves. Doc. 3403 at 16–17. This theory (which Plaintiffs did not even advance) is clearly erroneous: It impermissibly adds words to the regulation and disregards DEA's decision *not* to impose a "suspicious order" monitoring requirement on corporate pharmacy-registrants. "Where . . . particular language [is included] in one section . . . but omit[ted] . . . in another, it is generally presumed that [the drafter] acts intentionally and purposely in the disparate inclusion or exclusion." *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993); *see also, e.g.*, *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253–54 (1992) ("[C]ourts must presume that a legislature [or agency] says in a statute [or rule] what it means and means in a statute [or rule] what it says there."). If the requirement to keep certain records necessarily entailed an additional requirement to affirmatively *monitor* those records for suspicious orders, then 21 C.F.R. § 1301.74(b) (the suspicious-order-monitoring system requirement applicable to manufacturer- and distributor-registrants but *not* to pharmacy-registrants) would be superfluous. *See Hibbs v. Winn*, 542 U.S. 88, 101 (2004) ("[a] statute [or regulation] should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant"). The Court "ha[s] a duty to respect [a] legitimate policy choice[]" made by a political branch; here, that choice was to refrain from requiring pharmacy-registrants to implement a system to monitor for suspicious prescriptions. *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 866 (1984).

The obvious purpose of the record-keeping requirements is to make certain that records are available to law enforcement for *their* investigations. The CSA states this explicitly: "Every . . . record required under this section . . . shall be kept and be available, for at least two years, *for inspection and copying by officers or employees of the United States* authorized by the Attorney General." 21 U.S.C. § 827(b) (emphasis added); *see also* 21 C.F.R. § 1304.04(h) (requiring records to be maintained so that they are "readily retrievable . . . if requested by the [DEA] or other law enforcement agent"). There is no indication that Congress or DEA ever contemplated that the record-keeping requirement created a duty on the part of pharmacy-registrants to analyze aggregated prescription records for the purpose of undertaking their own investigations of potential unlawful diversion.

Precedent addressing the record-keeping requirements reinforces the conclusion that there is no implicit requirement that pharmacies aggregate and analyze their records (or otherwise affirmatively "use" them to prevent diversion). In *Medicine Shoppe-Jonesborough v. DEA*, 300 F. App'x 409 (6th Cir. 2008) (Sutton, J.)—a case on which this Court relied—the Sixth Circuit discussed the CSA's record-keeping requirements at length in upholding DEA's revocation of a pharmacy's registration for, among other things, falling short of its record-keeping obligation. *Id.* at 411–12. Nowhere did the Sixth Circuit mention the need for the pharmacy itself to make use of its records to affirmatively "check" for diversion—naturally, since no such requirement exists. Likewise, in *United States v. Green Drugs*, 905 F.2d 694 (3d Cir. 1990), the Third Circuit delved into the legislative history of the CSA and concluded that Congress considered the record-keeping requirements a way for the *government* to "monitor the drug transactions of registrants," to prevent registrants themselves from engaging in diversion. *Id.* at 698.

Grafting an implicit data-analysis requirement onto the regulatory record-keeping provisions is also clearly erroneous in view of the content and regulatory history of those requirements. As an initial matter, the only record-keeping regulation cited by the Court, 21 C.F.R. § 1304.22(c), does not require pharmacy-registrants to keep records that include the identity of the prescriber. Thus—contrary to what the Order assumed, *see* Doc. 3403 at 23–24—pharmacies could not, even in theory, use records maintained pursuant to that provision to detect suspicious prescribers. To be sure, a different regulation requires pharmacies to keep copies or other records of prescriptions filled, and each prescription includes the prescriber's identity. *See* 21 C.F.R. § 1304.04(h). But there is no requirement to digitize paper prescriptions; far from *requiring* that records be maintained on a computer medium, the regulations address what a registrant must do "if" it chooses to do so. *Id.* § 1304.04(b)(2). Consequently, there could be no implicit (and certainly there is no explicit) requirement to conduct data analysis of those prescriptions. Notably, electronic prescriptions for controlled substances were not even allowed until 2010—in a rule whose history is telling.

When DEA promulgated the rule authorizing electronic prescriptions for controlled substances, it never suggested that pharmacies were expected to use their electronic prescription application to engage in "data-driven analysis" (using the prescription records as the input for "[c]omputer algorithms") to check for "red flags" in "synergy" with their pharmacists. Doc. 3403 at 23–24 & n.27; *see* Interim Final Rule: Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,236-01 (Mar. 31, 2010) (in which the term "red flag" does not appear even once). Far from it. DEA *specifically rejected* the idea that "the intent of th[e] rule [was] to provide a mechanism" for "the generalized collection or analysis of controlled substance prescription data." *Id.* at 16,280–81. DEA made this statement in response to comments

proposing that DEA engage in analysis of prescription data "to reduce abuse." *Id.* There was no suggestion by anyone—and certainly no language in the rule—indicating that pharmacies were required to engage in such an analysis. Indeed, if, through this rulemaking, DEA had required pharmacies to "use" their "collect[ed] data," as mandated by this Court's Order, it would have been required to notify pharmacies of this requirement in the Notice of Proposed Rulemaking. It did not do so. *See generally* Notice of Proposed Rulemaking, Electronic Prescriptions for Controlled Substances, 73 Fed. Reg. 36,722 (June 27, 2008). DEA also would have been required to analyze the costs and benefits of that requirement. *See* Executive Order 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993) ("In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating."). No such analysis was performed. *See* 75 Fed. Reg. at 16,291–16,302.

2. The "effective controls against diversion" regulation does not imply a corporate duty to monitor for "red flag" prescriptions.

The Court reasoned that it would be inconsistent with the regulatory mandate that all registrants "provide effective controls and procedures to guard against theft and diversion" if pharmacy-registrants did not have a corporate-level obligation to monitor for suspicious prescriptions. Doc. 3403 at 25 (emphasis omitted). It determined that the regulation's use of the word "diversion" broadened its meaning beyond the security requirements it sets forth—security requirements which, in the Court's view, addressed only the "theft" prong of the requirement and not the "diversion" prong. This interpretation, however, is belied by the plain terms of the regulation. The regulation states expressly: "In order to determine whether a registrant has provided effective controls against *diversion*, the Administrator shall use the security requirements . . . as standards for the . . . operating procedures necessary to prevent *diversion*." 21 C.F.R. § 1301.71(a) (emphasis added). This language makes it crystal clear that the security

requirements (which are delineated in the subsequent sections of the rule and which do *not* include the Court's novel monitoring requirement, *see id.* §§ 1301.72–1301.76) are what is required to meet the "effective controls against diversion" requirement.

It is for DEA—not the Court—to write the rules on what controls against diversion are necessary. DEA has done just that in § 1301.71(a) and in the subsequent sections of the regulation setting forth security requirements. As the Court recognized in its Order, the section establishing the suspicious-order monitoring requirement, 21 C.F.R. § 1301.74(b), "applies specifically to non-practitioners—that is, manufacturers and distributors, but *not* pharmacies." Doc. 3403 at 13. DEA has elected not to impose a requirement to use data analysis to monitor for "suspicious" or "red flag" prescriptions. DEA's practice confirms what is already clear from the regulatory text: In the *Holiday CVS* adjudication, a DEA administrative law judge determined that "effective controls against diversion" encompasses only the security requirements enumerated in the regulation and is *not* a basis for challenging a pharmacy-registrant's dispensing. *See* Order on Hearing Scope & Gov't Mots. Regarding Resps.' Experts at 6–7, *Holiday CVS, L.L.C.*, Dkt. No. 12-37 & 12-38 (DEA ALJ Apr. 13, 2012), Doc. 3379-1. It is not the role of the Court to second-guess DEA's judgment and unilaterally rewrite the regulation. *See McKesson Corp.*, 2020 WL 4805034, at *5 (recognizing that the standard of § 1301.71 is "subject to discretionary interpretation by [DEA]").

The Court attempted to justify its decision to stray from the plain language of DEA's regulations with a misinterpretation of Pharmacy Defendants' argument. The Court accused Pharmacy Defendants of proposing "a frightening abdication of responsibility": that pharmacy-registrants "need only guard against theft" and not diversion. Doc. 3403 at 15. That is not Pharmacy Defendants' position at all.

To be clear, Plaintiffs' case is not about the many kinds of diversion that pharmacy-registrants are required to guard against, whether by protecting the physical security of their inventory or by employing licensed and reliable pharmacists. Instead, it is about something different—whether facially valid prescriptions written by authorized prescribers should have been filled. It is particularly difficult, if not impossible, to distinguish the issuance of such a prescription without a legitimate medical purpose from valid prescribing, since it may turn on only the secret and subjective intentions of a customer and a prescriber. DEA opted to guard against invalid prescriptions through the individualized professional judgment of pharmacists who are presented with prescriptions, not by an independent corporate-level layer of monitoring. Were it otherwise, DEA would allow only large chain pharmacies (the only type of pharmacies that potentially could detect meaningful signals of diversion through corporate-level aggregation and analysis) to dispense controlled substances. The fact that DEA has registered many small independent pharmacies that lack the capacity for aggregating data or employing sophisticated analytical algorithms confirms that there is no such requirement.

3. "Agency decisions" do not require corporate pharmacy-registrants to "identify red flags" through the analysis of prescription records.

The Court believed that unspecified "Agency decisions" "require[]" corporate pharmacy-registrants themselves, independent of their pharmacists, to "identify and resolve red flags before filling opioid prescriptions." Doc. 3403 at 22 & n.24, 25. The Court also apparently believed that the regulatory regime mandates that pharmacy-registrants implement "[c]omputer algorithms" to work "in synergy" with their pharmacists' professional judgments in detecting red flags. *Id*. at 23–24 & n.27. These conclusions are erroneous in at least four separate ways.

First, no DEA decision has ever said that corporate pharmacy-registrants (as opposed to their pharmacists) "are obligated to check for . . . red flags of possible diversion" before

dispensing any controlled substance. *Id.* at 22; *see also id.* at 14. The Court observed that DEA expert witnesses have conducted an after-the-fact "red flag analysis" as evidence in enforcement cases and that DEA has used the language of "red flags" to describe how a violation of the corresponding responsibility may be proved. *Id.* at 22. But allowing this form of trial proof does not remotely create a requirement that pharmacy-registrants *themselves* conduct a computerized red-flag analysis before they allow their pharmacists to exercise their professional judgment to fill incoming prescriptions.

Not a single DEA opinion holds that such a duty exists. In every DEA opinion finding a violation, it is the underlying dispensing that is the basis for the CSA violation, not (as the Court supposed) a pharmacy's failure to maintain a sufficient corporate-level system for checking prescriptions for red flags. *See, e.g.*, *Superior Pharmacy*, 81 Fed. Reg. 31,310-01, 31,334 (DEA May 18, 2016) (finding Government's evidence, including red-flag analysis, "insufficient to establish that [corporate pharmacy-registrant's] pharmacists violated their corresponding responsibility when they dispensed the prescriptions at issue"); *JM Pharmacy Grp., Inc. d/b/a Farmacia Nueva and Best Pharma Corp.*, 80 Fed. Reg. 28,667-01, 28,670–72 & n.21 (DEA May 19, 2015) (explaining that the term "red flag" does not appear in any statute or regulation and that the government must ultimately establish knowledge or willful blindness with respect to whether prescriptions lacked a legitimate medical purpose).

Second, the Court cites DEA decisions for the proposition that corporate pharmacy-registrants—separate and apart from their pharmacists—have a legal "responsibility" to identify so-called "red flags" of potential diversion. Doc. 3403 at 18, 25. But the unambiguous text of 21 C.F.R. § 1306.04(a) assigns the "corresponding responsibility" for proper prescribing and dispensing to "*the pharmacist who fills the prescription*," without any reference to the pharmacy-

registrant. An agency cannot amend its regulation through dicta accompanying adjudications. *See, e.g.*, *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 101 (2015) (agencies must use the same procedures to amend a rule as they used to issue the rule). Even if the Court were correct that DEA adjudications have described a "corresponding responsibility" resting directly (not just vicariously) on pharmacies to identify and resolve red flags independently of their pharmacists, *see* Doc. 3403 at 22 n.24, the Court could not properly defer to that purported misinterpretation because the regulation is unambiguous. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) ("If uncertainty does not exist, there is no plausible reason for deference. The regulation then just means what it means—and the court must give it effect, as the court would any law.").

Contrary to what the Order suggested, *see* Doc. 3403 at 18–19, *Appalachian Regional Healthcare* provides no support for construing § 1306.04(a) as assigning the "corresponding responsibility" not only to the pharmacist but also to the pharmacy. The court in that case rejected an argument that the word "person" in the last sentence of § 1306.04(a) should be understood to mean only "pharmacist" or "prescribing practitioner," even though DEA regulations define "person" more broadly. *See United States v. Appalachian Reg'l Healthcare*, 246 F. Supp. 3d 1184, 1189 (E.D. Ky. 2017). The court explained that it found "nothing inconsistent about articulating the responsibilities of individual [prescribing] practitioners and pharmacists" on the one hand "while simultaneously indicating that *other entities* [e.g., a pharmacy-operating corporation] may be subject to penalties for their role in issuing and filling invalid prescriptions," if they do so knowingly. *Id.* at 1189–90 (emphasis added). The court thus specifically rejected the position taken by the Order, that the sentence assigning the "corresponding responsibility" refers to anyone other than the individual pharmacist. Most importantly, neither the *Appalachian Regional Healthcare* court nor any other court has ever

suggested that this language insinuates an unwritten duty—absent from the CSA and its implementing regulations—to engage in "red flag" data analysis or that a "pharmacy-operating corporation" can be said to knowingly fill an invalid prescription through a failure to engage in such data analysis.

Third, insofar as the Court is concerned that the "fundamental purpose of the Act" would be "turn[ed] on its head" if it abided by the Act's plain text, Doc. 3403 at 14, the Court overlooks Agency decisions applying *respondeat superior* to ensure "that pharmacy owners who are not themselves pharmacists are [not] absolved of responsibility for their own dispensing practices simply because they must employ a pharmacist," *id.* at 20 (emphasis omitted). As Pharmacy Defendants explained, pharmacy-registrants *are* subject to sanctions for the unlawful dispensing of pharmacists acting within the scope of their employment. *See* Doc. 3379 at 9 & n.9. Under the CSA, a pharmacy risks the loss of its registration and steep civil penalties if it allows its pharmacists to dispense controlled substances while turning a blind eye to indicia of diversion. The very Agency decisions referenced by the Court therefore render its concerns about pharmacy-registrant immunity unfounded. *See* Doc. 3403 at 21 n.21.

Finally, in requiring corporate-level data analysis, the Court ignores the Agency decisions that hold that the "corresponding responsibility" may be violated only if a "red flag" associated with a prescription is actually "recognizable" to the pharmacist presented with the prescription. *Holiday CVS*, 77 Fed. Reg. 62,316-01, 62,344–45 & n.105 (DEA ALJ Apr. 13, 2012); *see also id.* at 62,332 (DEA's expert defined "red flags" as "*circumstances surrounding the presentation of a prescription to a pharmacist* . . . that can create an obligation on the part of a reasonable pharmacist to decline to fill, or to take other action in the exercise of the pharmacist's professional judgment" (emphasis added)). The Court's reasoning is premised on

an altogether different view—found nowhere in the CSA, its implementing regulations, or any cases interpreting them—that red flags "include indicia that would be very difficult, if not impossible, for a human pharmacist to identify consistently absent a system to aggregate, analyze, and provide feedback to the pharmacist about the prescription" and that, indeed, certain "red flags are patterns in prescription data that a human pharmacist normally would never see." Doc. 3403 at 23 & n.27. This stands in sharp contrast to agency jurisprudence, which indicates that a "red flag," by definition, must be "recognizable" to the pharmacist. In *Holiday CVS*, for example, the "pattern prescribing" involved customers presenting similar prescriptions *on the same day*, and DEA acknowledged that a finding of a pattern-prescribing red flag would require evidence of "knowledge of the presentation of the similar prescriptions on that day." *Id.* at 62,345 n.105; *see also id.* at 62,333 (noting evidence that on one day, there were eight controlled-substance dispensing events where, among other things, "like varieties and strengths of medications were dispensed for all but one patient . . . and the common prescriber for all eight patients had a listed practice address in Fort Lauderdale, Florida," over 200 miles away from the pharmacy in Sanford, Florida). DEA further noted that pharmacists at the respondent stores admitted to investigators that they had observed pattern prescribing by certain physicians. *Id.* at 62,330, 62,344. In short, DEA considers indicia like "pattern prescribing" to be "red flags" *only if* they are recognizable to a human pharmacist. DEA has never even suggested, much less required, a "global mechanism for reference to other prescriptions" to check for patterns potentially indicating improper prescribing. Doc. 3403 at 23.

For each of these independently sufficient reasons, it is manifestly clear that "Agency decisions" do not "require[]" corporate pharmacy-registrants, independent of their pharmacists, to "identify and resolve red flags before filling opioid prescriptions." *Id.* at 22 & n.24, 25.

B. The Court Should Reconsider Its Holding That the *Morris* Rule of Statutory Construction Applies to Ohio Rev. Code § 4729.35.

The Court also erred by applying *State ex rel. Morris v. Sullivan*, 90 N.E. 146 (Ohio 1909), to conclude that Ohio Rev. Code § 4729.35 does not preclude Plaintiffs' public nuisance claim. *See* Doc. 3403 at 5–7. *Morris* provides that statutes should be interpreted "in the light of and with reference to the rules and principles of the common law in force at the time of their enactment, and . . . the Legislature will not be presumed or held to have intended a repeal of the settled rules of the common law, unless the language employed by it clearly expresses or imports such intention." *Morris*, 90 N.E. at syllabus ¶ 3. But the scope of *Morris* is narrow, and it is inapplicable to Ohio Rev. Code § 4729.35, which directly addresses the remedies available for a "public nuisance" based on an alleged violation of laws governing the distribution of drugs of abuse.

Importantly, as then-Justice (now Judge) Cook has explained, *Morris* "did not involve the codification of causes of action previously known at common law." *Carrel v. Allied Prods. Corp.*, 677 N.E.2d 795, 802 (Ohio 1997) (Cook, J., dissenting in part and concurring in part). It instead concerned the lawfulness of an outgoing governor's January appointment of a new railroad commissioner to a position that would not become vacant until after the governor left office. *Morris*, 90 N.E. at 148. The Ohio Supreme Court noted the common law rule that "an officer clothed with authority to appoint to a public office cannot, in the absence of express statutory authority, make a valid appointment thereto for a term which is not to begin until after the expiration of the term of such appointing officer." *Id.* at 148–49. Although the statute creating the railroad commission required appointments to be made in January, the common law rule that limited the governor's appointment authority was not abrogated because the statute "neither in express terms, nor by necessary implication . . . imposes or enjoins upon the outgoing Governor the duty of making such appointment." *Id.* at 150. Put differently, the statute did not

address the question directly—its subject matter was merely "tangential to a rule of common law." *Carrel*, 677 N.E.2d at 802.

Morris has nothing to say about the construction of a statute that, like Ohio Rev. Code § 4729.35, "codifi[es] [a] common-law cause[] of action." *Id.*; *see also Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 920 n.6 (N.D. Ohio 2009) (Justice Cook's "dissenting opinion in *Carrel* makes a strong argument that based upon earlier Ohio Supreme Court precedents (which the majority did not distinguish or overrule) the rule of statutory construction applicable in this context is considerably less exacting than the standard articulated by the majority."). For that reason, Ohio courts have consistently applied *Morris* only where the statutory provision at issue may fairly be characterized as "tangential" to underlying common law. *See, e.g.*, *Ohioans for Concealed Carry v. City of Columbus*, 140 N.E.3d 1215, 1230 (Ohio Ct. App. 2019) (a statute that "makes no mention of standing" did not "abrogate[] common law requirements for standing" (citations omitted)); *Mann v. Northgate Inv'rs, L.L.C.*, 5 N.E.3d 594, 599 (Ohio 2014) (Ohio Rev. Code § 5321.04, a statute establishing landlord obligations, did not modify the common-law rule that "a landlord owes a tenant's guest the same duty that the landlord owes the tenant"); *Smith v. Mitchell*, 520 N.E.2d 213, 239 (Ohio 1988) (Ohio Rev. Code § 2711.21(D)—authorizing a party to "subpoena any member or members of the arbitration board for purposes of cross-examination" in the context of certain medical claims—did not "clearly express[] an intention . . . to strip away a litigant's common-law right to cross-examine an adverse witness"); *Seasongood v. Seasongood*, 27 Ohio C.D. 200, 202–03 (Ohio Ct. App. 1915) (common-law rule that "the executor named in the will, if not incompetent, must be appointed" controlled where statute did "not expressly forbid a nonresident of the state being appointed executor").

Rather than relying on the *Morris* rule, then, the Court should have given Ohio Rev. Code § 4729.35 its plain meaning, in light of the General Assembly's comprehensive scheme governing the distribution and dispensing of drugs of abuse: The remedy for a "public nuisance" based on an alleged violation of laws governing the distribution of drugs of abuse is injunctive relief.

II. At Minimum, the Court Should Certify the Federal Questions for Interlocutory Appeal and the State-Law Question to the Ohio Supreme Court.

If the Court will not reconsider its Order, it should certify the Order for interlocutory appeal so that the Sixth Circuit can resolve the controlling and significant questions raised above about the scope of pharmacies' duties under the CSA and certify the state-law statutory construction question to the Ohio Supreme Court.

A. The Preconditions Are Satisfied for an Interlocutory Appeal to Address the Nature and Scope of Pharmacy Duties Under the CSA.

An order is properly certified for interlocutory appeal under 28 U.S.C. § 1292(b) if: "[1] [it] involves a controlling question of law [as] to which there is [2] substantial ground for difference of opinion and . . . [3] an immediate appeal may materially advance the termination of the litigation." *In re Trump*, 874 F.3d at 951 (emphasis omitted).

The issues of statutory and regulatory interpretation addressed above are controlling questions of law in these cases. As an initial matter, whether the CSA imposes "duties" at the corporate level to "maintain systems, policies, or procedures to identify prescriptions that bear indicia ('red flags') that the prescription is invalid, or that the prescribed drugs may be diverted for illegitimate use," Doc. 3403 at 21–22, is a "pure question[] of law" that does not involve "any determination of any facts," *Kollaritsch v. Mich. State Univ. Bd. of Trs.*, 944 F.3d 613, 619 (6th Cir. 2019). Both the Court and Plaintiffs' counsel have characterized these cases as "systems" cases. If there is no requirement for a system, their dispensing claims are not viable. Doc. 3113

at 6–11. More specifically, an absolute nuisance requires proof of either culpable unlawful conduct or culpable intentional conduct. *See, e.g.*, *Barnett v. Carr*, No. CA2000-11-219, 2001 WL 1078980, at *10–11 (Ohio Ct. App. Sept. 17, 2001). If Plaintiffs cannot establish unlawful conduct, then their absolute nuisance claim fails unless they could somehow prove that a Pharmacy Defendant "intended to bring about the conditions which are in fact found to be a nuisance." *Nottke v. Norfolk S. Ry. Co.*, 264 F. Supp. 3d 859, 863 (N.D. Ohio 2017); *see* Doc. 3379 at 14. A legal issue is controlling if it "could materially affect the outcome of the case"; the legal issues identified here not only could materially affect the outcome but are all but certain to do so. *In re City of Memphis*, 293 F.3d 345, 351 (6th Cir. 2002).

These issues are also questions of first impression on which there is, at best, substantial ground for difference of opinion. *See In re Trump*, 874 F.3d at 952 (there is "substantial ground for difference of opinion" where "fair-minded jurists might reach contradictory conclusions"). The Court itself has recognized that the scope of dispensing obligations under the CSA is a novel question that may be appropriate for certification. *See* Tr. of Case Management Conf. (Dec. 4, 2019) at 38. The Court also acknowledged in its Order that it is "not . . . clear what a pharmacy-registrant must do with the prescription data it must collect." Doc. 3403 at 24. And while many other decisions address the statutory and regulatory provisions at issue, none ever has read them as the Court did here. To the contrary, and in direct conflict with the Court's holding, another district court recently held that the "effective controls" regulation "does *not* require any specific security measures." *McKesson Corp.*, 2020 WL 4805034, at *4 (emphasis added). Further demonstrating the substantial grounds for differences of opinion, Pharmacy Defendants simultaneously are facing potential class actions alleging that their policies, procedures, and systems are *too* restrictive to pain patients. *See* Complaint, *Smith v. Walgreens Boots All., Inc. et*

al., No. 3:20-cv-5451 (N.D. Cal. Aug. 6, 2020); Complaint, *Fuog v. CVS Pharmacy, Inc. et al.*, No. 1:20-cv-337 (D.R.I. Aug. 6, 2020).

Finally, an immediate appeal will materially advance the ultimate termination of this litigation. If the Court is wrong about the nature and scope of Pharmacy Defendants' obligations under the CSA, then the Track 3 bellwether will be of no value to the ultimate resolution of the MDL. It would turn entirely on the alleged violation of obligations that do not exist. An immediate appeal would also sharpen the focus of discovery. If the Sixth Circuit concludes that a dispensing "systems" duty does not exist before substantial resources are expended on discovery pertaining to that supposed duty, much waste would be avoided. The time needed for the Sixth Circuit to resolve the appeal, moreover, would largely coincide with the currently scheduled Track 1B trial, so the bellwether litigation would continue to advance, and Track 3 will not be substantially delayed, if at all.

All preconditions to certification of an interlocutory appeal are therefore satisfied, and the Court should certify an appeal if it does not reconsider.

B. Certification to the Ohio Supreme Court Is Also Appropriate.

Whether Ohio Rev. Code § 4729.35 precludes an absolute public nuisance cause of action for abatement or damages based on an alleged violation of the controlled-substance laws implicates the meaning of an Ohio statute, the content of Ohio common law, and an Ohio principle of statutory construction. Rather than "speculate how [the] state [supreme] court[] w[ould] decide [these] important questions of state law," the Court should certify the question to the Ohio Supreme Court. *Grover*, 33 F.3d at 719. Because the question is determinative of Plaintiffs' public nuisance claim and because, as explained *supra* pp. 19–20, there is no

controlling Ohio Supreme Court precedent, the state court's certification procedure is available. Ohio S. Ct. Prac. R. 9.01.

CONCLUSION

For the foregoing reasons, Pharmacy Defendants ask the Court to reconsider its Order and grant their motion to dismiss. Alternatively, Pharmacy Defendants ask the Court to certify its Order for interlocutory appeal under 28 U.S.C. § 1292(b) and certify to the Ohio Supreme Court the question whether Ohio Rev. Code § 4729.35 precludes an absolute public nuisance cause of action for abatement or damages based on an alleged violation of the controlled-substance laws.

Dated: August 25, 2020

Respectfully submitted,

/s/ *Tara A. Fumerton*

Tara A. Fumerton
Tina M. Tabacchi
JONES DAY
77 West Wacker
Chicago, IL 60601
Phone: (312) 269-4335
Fax: (312) 782-8585
E-mail: tfumerton@jonesday.com
E-mail: tmtabacchi@jonesday.com

John M. Majoras
Benjamin C. Mizer
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001
Phone: (202) 879-3939
Fax: (202) 626-1700
E-mail: jmmajoras@jonesday.com
E-mail: bmizer@jonesday.com

Attorneys for Walmart Inc. f/k/a Wal-Mart Stores, Inc.; Wal-Mart Stores East, LP; WSE Management, LLC; WSE Investment LLC; and Wal-Mart Stores East, Inc.

/s/ *Alexandra W. Miller* (consent)
Alexandra W. Miller
Eric R. Delinsky
ZUCKERMAN SPAEDER LLP
1800 M Street, NW
Suite 1000
Washington, DC 20036
Phone: (202) 778-1800
Fax: (202) 822-8106
E-mail: smiller@zuckerman.com
E-mail: edelinsky@zuckerman.com

Attorneys for CVS Health Corporation; CVS Pharmacy, Inc.; CVS Indiana, L.L.C.; CVS Rx Services, Inc.; CVS TN Distribution, L.L.C.; and Ohio CVS Stores L.L.C.

/s/ *Kelly A. Moore* (consent)
Kelly A. Moore
MORGAN, LEWIS & BOCKIUS LLP
101 Park Avenue
New York, NY 10178
Phone: (212) 309-6612
Fax: (212) 309-6001
E-mail: kelly.moore@morganlewis.com

John P. Lavelle, Jr.
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103
Phone: (215) 963-4824
Fax: (215) 963-5001
E-mail: john.lavelle@morganlewis.com

Attorneys for Rite Aid Corp.; Rite Aid Hdqtrs. Corp.; Rite Aid of Ohio, Inc.; Rite Aid of Maryland, Inc.; and Eckerd Corp. d/b/a Rite Aid Liverpool Distribution Center

/s/ *Kaspar J. Stoffelmayr* (consent)
Kaspar J. Stoffelmayr
Katherine M. Swift
BARTLIT BECK LLP
54 West Hubbard Street
Chicago, IL 60654
Phone: (312) 494-4400

Fax: (312) 494-4440
E-mail: kaspar.stoffelmayr@bartlitbeck.com
E-mail: kate.swift@bartlitbeck.com

Attorneys for Walgreen Boots Alliance, Inc.; Walgreen Co.; and Walgreen Eastern Co.

/s/ *Robert M. Barnes* (consent)
Robert M. Barnes
Scott D. Livingston
Joshua A. Kobrin
MARCUS & SHAPIRA, LLP
35th Floor, One Oxford Centre
301 Grant Street
Pittsburgh, PA 15219
Phone: (412) 471-3490
Fax: (412) 391-8758
E-mail: rbarnes@marcus-shapira.com
E-mail: livingston@marcus-shapira.com
E-mail: kobrin@marcus-shapira.com

Attorneys for Giant Eagle, Inc., and HBC Service Company

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record on August 25, 2020.

/s/ *Tara A. Fumerton*
Tara A. Fumerton
JONES DAY
77 West Wacker
Chicago, IL 60601
Phone: (312) 269-4335
Fax: (312) 782-8585
E-mail: tfumerton@jonesday.com

Counsel for Walmart Inc.